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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,576	03/29/2002	Karen M Lammers	092271-9013	2520
7590	02/24/2004			
Timothy M Kelley Michael Best & Friedrich 100 East Wisconsin Avenue Milwaukee, WI 53202-4108			EXAMINER JONES, DWAYNE C	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/089,576		LAMMERS, KAREN M	
	Examiner		Art Unit	
	Dwayne C Jones		1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>03FEB03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 1- 34 are pending.
2. Claims 1-34 are rejected.

Response to Arguments

3. Applicant's arguments filed November 7, 2003 have been fully considered but they are not persuasive. Applicant presents the following arguments. First, applicant alleges that Gregory et al. disclose of a plethora of compounds to treat a variety of disease states, inter alia alopecia. Second, applicant argues that Gregory et al. is not enabled to treat alopecia since Gregory et al. provides no indication of what an effective amount would be to treat hair loss as well as the frequency of administration. Third, applicant purports that Billups is directed to minoxidil and makes no mention of effective dosages of the claimed compounds. Fourth, applicant further alleges that there is no teaching or suggestion in the prior art to make the claimed composition. Fifth, applicant further argues that Gregory et al. and Billups, taken separately or combined, do not enable a method of treating hair loss, and do not teach, suggest or enable an effective amount of a composition for achieving this goal. Sixth, applicant argues that this transitional language of "consisting essentially of" excludes cyclooxygenase-2 inhibitors because Gregory et al. teach of a composition that is composed of a 5-lipoxygenase inhibitor and a cyclooxygenase-2 inhibitor.

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4. First, applicant alleges that Gregory et al. disclose of a plethora of compounds to treat a variety of disease states, inter alia alopecia. Gregory et al. disclose that 5-lipoxygenase inhibitors are useful in the treatment of autoimmune and inflammatory diseases, specifically this includes alopecia, (see column 5, lines 7-12, column 6, lines 1-6, and column 13, lines 6-8, and 26).

5. Moreover, applicant argues that Gregory et al. is not enabled to treat alopecia since Gregory et al. provides no indication of what an effective amount would be to treat hair loss as well as the frequency of administration. The instant invention defines "the effective amount" from "about 5mg to about 3000mg". In response to this argument it is noted that Gregory et al. define and provide enablement for the amount of therapeutically active compounds. In fact, Gregory et al. state that these 5-lipoxygenase inhibitors are administered and the dosage regimen for treating a disease condition with these particular compounds depends on a variety of factors, including the age, weight, and sex of the individual, the route and frequency of administration. Gregory et al. also specifically teach that the pharmaceutical composition of an active agent is present in the range of about 0.1 mg to 2000mg, (see column 34, lines 45-52).

6. Next, applicant purports that Billups is directed to minoxidil and makes no mention of effective dosages of the claimed compounds. However, it is mentioned that the prior art reference of Billups is utilized in a combined rejection under 35 U.S.C. 103(a) as being obvious over Gregory et al. *in view of* Billups, see *In re Kerkhoven*, 626, F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). For this reason, the prior art reference of Billups is employed to teach that the pharmaceutical of minoxidil is used as

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a hair growth stimulant and to treat baldness, (see page 488, 1st column). In addition, it is well within the level of the skilled artisan to determine therapeutically effective amounts, dosages, as well as modes and methods of administration in order to deliver the optimum therapeutic amount of the pharmaceutical active agent.

7. Applicant further alleges that there is no teaching or suggestion in the prior art to make the claimed composition. Since both prior art teachings are directed to treating the same condition, in particular alopecia, it would have been obvious to one having ordinary skill in the art to combine these two teachings and arrive at the instantly claimed compositions and methods of using. By combining these two teachings that are used for the very same condition it logically follows to combine two pharmaceuticals into a combined composition for treating the same condition.

8. Applicants further argue that Gregory et al. and Billups, taken separately or combined, do not enable a method of treating hair loss, and do not teach, suggest or enable an effective amount of a composition for achieving this goal. The instant rejection is the result of Gregory et al. in combination with Billups. Both references teach of compounds to effectively and therapeutically treat the very same condition of alopecia. The skilled artisan is clearly provided with the motivation to therapeutically administer the pharmaceutically active agent in an amount ranging from about 0.1mg to about 2000mg, (see column 34, lines 45-52 of Gregory et al.). Accordingly, the prior art references of record do in fact suggest and enable the skilled artisan with guidance to arrive at the instantly claimed invention.

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9. Applicant attempts to change the scope of the claims 22, 23, 29, and 33 with the incorporation of the transitional language of "consisting essentially of". In particular, applicant argues that this transitional language of "consisting essentially of" excludes cyclooxygenase-2 inhibitors because Gregory et al. teach of a composition that is composed of a 5-lipoxygenase inhibitor and a cyclooxygenase-2 inhibitor. However, the prior art reference of Gregory et al. still discloses that 5-lipoxygenase inhibitors are useful in the treatment of autoimmune and inflammatory diseases, specifically this includes alopecia, (see column 5, lines 7-12, column 6, lines 1-6, and column 13, lines 6-8, and 26). One having ordinary skill in the art is still provided with the teachings and motivation to use the compounds of Gregory et al. to treat hair loss along with the teachings of Billups, which is also directed to treating hair loss. Accordingly, the instantly filed claims are still rendered obvious over the prior art rejections of Gregory et al. in view of Billups.

Information Disclosure Statement

10. The disclosure statement filed February 3, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The nonpatent literature references were not provided in this IDS submission.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 14-17, 22, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The compound depicted in claim 14 has the following anomaly that renders the claim vague and indefinite. The valence of the oxygen atom of the carbonyl moiety is exceeded with the incorporation of the variable of R. For these reasons these claims are unclear and indefinite.

13. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 is rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph. The claim(s) must be in one sentence form only.

14. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 makes reference to the compound, which is not embraced by claim 22. Lack of antecedent basis.

15. Claim 23 recites the limitation "the compound has the structure" in lines 1-3 of claim 23. There is insufficient antecedent basis for this limitation in the claim because independent claim 22 does not possess the structure depicted in claim 23, namely the alkoxy moiety.

Claim Rejections - 35 USC § 103

16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

17. The rejection of claims 1-9, 12-23, 26-29, 32, and 33 under 35 U.S.C. 103(a) as being unpatentable over Gregory et al. of U.S. Patent No. 6,376,528 in view of Billups, N. F. of the American DRUG INDEX 1998, 42nd Edition is maintained and repeated.

Gregory et al. teach of treating alopecia with the "preferred" pharmaceutical of tenidap, (see column 13, line 26 and column 14, lines 33 and 34). In addition, the indolyl compound of claims 12-23 is simply the tautomer of the indolyl compound of claims 1-

11. The skilled artisan is clearly provided with the motivation to therapeutically administer the pharmaceutically active agent in an amount ranging from about 0.1mg to about 2000mg, (see column 34, lines 45-52 of Gregory et al.). Accordingly, it is well within the purview of the skilled artisan to synthetically manufacture a compound as well as its tautomeric isomers. Billups, N. F. specifically teach that the pharmaceutical of minoxidil is used as a hair growth stimulant and to treat baldness, (see page 488, 1st column). "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). For these reasons, it would have been obvious to one having ordinary skill in the art to combine these two pharmaceuticals to

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treat the very same ailment, namely alopecia. In addition, the skilled artisan would have been motivated to combine these prior art teachings to treat the very same condition.

18. In addition, applicant attempts to change the scope of the claims 22, 23, 29, and 33 with the incorporation of the transitional language of "consisting essentially of". In particular, applicant argues that this transitional language of "consisting essentially of" excludes cyclooxygenase-2 inhibitors because Gregory et al. teach of a composition that is composed of a 5-lipoxygenase inhibitor and a cyclooxygenase-2 inhibitor.

However, the prior art reference of Gregory et al. still discloses that 5-lipoxygenase inhibitors are useful in the treatment of autoimmune and inflammatory diseases, specifically this includes alopecia, (see column 5, lines 7-12, column 6, lines 1-6, and column 13, lines 6-8, and 26). One having ordinary skill in the art is still provided with the teachings and motivation to use the compounds of Gregory et al. to treat hair loss along with the teachings of Billups, which is also directed to treating hair loss.

Accordingly, the instantly filed claims are still rendered obvious over the prior art rejections of Gregory et al. in view of Billups.

19. Claims 1-34 under 35 U.S.C. 103(a) as being unpatentable over Gregory et al. of U.S. Patent No. 6,376,528 in view of Billups, N. F. of the American DRUG INDEX 1998, 42nd Edition is maintained and repeated. Gregory et al. teach of treating alopecia with the "preferred" pharmaceutical of tenidap, (see column 13, line 26 and column 14, lines 33 and 34). In addition, the indolyl compound of claims 12-23 is simply the tautomer of the indolyl compound of claims 1-11. The prior art compound of Gregory et al. teach inter alia, the use of the compound of tenidap. Applicants have attempted to limit claims

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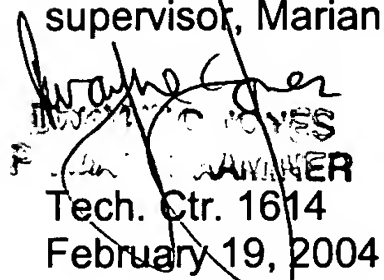
10, 11, 24, and 34 with the exclusion of the compound of tenidap. One having ordinary skill in the art would have been clearly motivated to select compounds that are structurally related to the well-known compounds of tenidap for treatment of alopecia because slight modifications with substituents, such as one halogen atom for another or a even a methyl group attached to an amino group of tenidap would not significantly alter the properties of the compound of the reference. In addition, the skilled artisan is clearly provided with the motivation to therapeutically administer the pharmaceutically active agent in an amount ranging from about 0.1mg to about 2000mg, (see column 34, lines 45-52 of Gregory et al.). Accordingly, it is well within the purview of the skilled artisan to synthetically manufacture a compound as well as its tautomeric isomers. Billups, N. F. specifically teach that the pharmaceutical of minoxidil is used as a hair growth stimulant and to treat baldness, (see page 488, 1st column). "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). For these reasons, it would have been obvious to one having ordinary skill in the art to combine these two pharmaceuticals to treat the very same ailment, namely alopecia. In addition, the skilled artisan would have been motivated to combine these prior art teachings to treat the very same condition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-

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0578. The examiner can normally be reached on Mondays, Tuesdays, Thursday, and Fridays from 8:30 am to 6:00 pm. The official fax No. for correspondence is (703) 872-9306.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, may be reached at (571) 272-0584.


MARIANNE SEIDEL
Tech. Ctr. 1614
February 19, 2004